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IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

COLLAGEN CORPORATION,
Petitioner,

v.

CHARLOTTE KENNEDY, *et al.*,
Respondents.

Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

---

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether 21 U.S.C. § 360k(a) preempts common law claims challenging the safety or effectiveness of a medical device that the Food and Drug Administration has found to be safe and effective and has approved for marketing pursuant to the premarket approval process under 21 U.S.C. 360e(c).*

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* Petitioner Collagen Corporation has no parent corporation and no non-wholly owned subsidiaries.

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---

PETITION FOR WRIT OF CERTIORARI

Collagen Corporation ("Collagen") hereby petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals is reported at 67 F.3d 1453 (App., *infra*, pp. 1a-19a). The order of the district court is not reported (App., *infra*, pp. 20a-21a). The unpublished opinions of the court of appeals on a prior appeal are cited at 967 F.2d 587 and 974 F.2d

1342 (App., *infra*, pp. 22a-30a, 31a-32a). The earlier order of the district court preceding that first appeal is not reported (App., *infra*, pp. 33a-37a).

JURISDICTION

The judgment of the court of appeals was filed on October 17, 1995. A timely petition for rehearing with suggestion for rehearing *en banc* was denied on January 16, 1996 (App., *infra*, p. 38a). The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTE AND REGULATION INVOLVED

21 U.S.C. § 360k(a) (Supp. 1995) in pertinent part provides:

> . . . no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 C.F.R. § 808.1(d) (1996) in pertinent part provides:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements ap-

plicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirements relates either to other products in addition to devices (*e.g.*, requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

STATEMENT

1. Company History and Regulatory Background.

In the early 1970s a group of biochemists and physicians at Stanford University developed a purified form of bovine collagen, a natural protein that provides structural support for skin, muscles, tendons, and bones. Together with other investors, they organized petitioner Collagen Corporation to manufacture and distribute collagen products to be used in various medical treatments. The product at issue in this case, Zyderm® Collagen Implant ("Zyderm"), is injected under the skin to correct or improve soft tissue deficiencies that arise from disease, trauma, or aging.

Zyderm is classified by the Food and Drug Administration ("FDA") as a Class III medical device subject to regulation under the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §§ 360c-360*l*. "Class III devices must generally undergo premarket approval (PMA) before the FDA will allow them into the marketplace." *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1339 (11th Cir. 1995), *cert. granted*, 116 S. Ct. 806 (January 19, 1996) (Nos. 95-754 and 95-886). The premarket approval process under 21 U.S.C. § 360e(c) (the "PMA process") is central to the statutory objective of

ensuring that all medical devices on the market afford "reasonable assurance of safety and effectiveness." 21 U.S.C. § 360c(1)(c). Before the FDA approves a Class III device for marketing pursuant to the PMA process, it determines that the device is safe and effective with respect to (1) the persons for whose use the device is intended and (2) the conditions of use prescribed, recommended, or suggested in the labeling of the device. 21 U.S.C. § 360c(2).

The PMA process is not the exclusive means by which Class III medical devices enter the market. The MDA provides three alternative routes to marketability: premarket approval is not required for (1) devices on the market prior to the effective date of the MDA, (2) devices found to be substantially equivalent to a device already on the market, or (3) devices entitled to the investigational device exemption. *See* 21 U.S.C. §§ 360e (b)(1)(A) and (B), 360j(g). But premarket approval is the statutory paradigm, and "the MDA contemplates that most Class III devices will reach the market through the PMA process." *Lohr*, 56 F.3d at 1340; *see* 21 U.S.C. § 360e(a).

The PMA process entails an exhaustive investigation into safety and effectiveness. An applicant who seeks the FDA's approval to market a Class III device must provide:

> (A) full reports of all information, published or known to . . . the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;
>
> (B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;
>
> (C) a full description of the methods used in, and the facilities and controls used for, the manufacture [and] processing . . . of such device;

> (D) . . . adequate information to show that . . . such device fully meets [pertinent] performance standard[s]. . .;
>
> (E) . . . samples of such device . . .;
>
> (F) specimens of the labeling proposed to be used for such device; and
>
> (G) such other information . . . as the [FDA] . . . may require.

21 U.S.C. § 360e(c)(1).

The application for premarket approval also must include, *inter alia*, a "general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended," an "explanation of how the device functions, the basic scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device," and a "description of existing alternative practices or procedures for diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended." 21 C.F.R. § 814.20(b)(3). The application must be periodically updated "with new safety and effectiveness information learned about the device from ongoing or completed studies." 21 C.F.R. § 814.20(e).

A completed application is reviewed by a panel of experts. 21 U.S.C. § 360(c)(2). After considering the panel's report and recommendation, the FDA will grant the application only if it finds reasonable assurance (1) that the device is safe and effective with respect to both the person for whose use the device is intended and the conditions of use prescribed, recommended, or suggested in its labeling, (2) that the manufacturing and processing methods and facilities are satisfactory, and (3) that the proposed labeling is not false or misleading in any manner. 21 U.S.C. §§ 360c(2) and 360e(d)(2); *see also* 21 C.F.R. § 814.44.

Collagen filed an application with the FDA for premarket approval of Zyderm on April 30, 1980. Its application included, *inter alia*, the results of clinical testing in more than five thousand human subjects. Erickson Decl., Ex. 2 ("Erickson Decl." refers to a declaration submitted by Collagen in support of summary judgment). Following more than one year of detailed investigation, the FDA found Zyderm to be safe and effective and approved it for marketing. 46 Fed. Reg. 46394 (1981). The FDA's approval order for Zyderm set forth numerous "conditions of approval," including the following:

> *Before making any change that may affect the safety or effectiveness* of the device, [Collagen must] submit a supplemental PMA for review and approval by FDA. Such changes include, but are not limited to:
>
> (1) new indications for use;
>
> (2) labeling changes;
>
> (3) changes in manufacturing facilities, methods or quality control procedures, and involvement of new subcontractors, suppliers, or distributors;
>
> (4) changes in sterilization procedures;
>
> (5) changes in packaging;
>
> (6) changes in performance or design specifications, circuits, parts, components, accessories, ingredients, or physical layout of the device.

Erickson Decl., Ex. 10 (emphasis in original).

Since 1981, Collagen has marketed Zyderm as a prescription-only medical device strictly in accordance with these conditions and other requirements imposed by the FDA. During this time, and as required by regulation, Collagen has furnished the FDA with information about "unpublished reports of data from any clinical investigatons or nonclinical laboratory studies involving the device" and "[r]eports in the scientific literature concerning the device." 21 C.F.R. § 818.84(b)(2). In 1991,

after ten years of clinical experience, the FDA undertook a review of Zyderm's record. Erickson Decl. at 4. At the conclusion of that review, the FDA reaffirmed its finding of safety and effectiveness. *Id.*

2. Proceedings in This Case.

On at least three occasions in 1982, respondent Charlotte Kennedy received injections of Zyderm as treatment for facial wrinkles. Her physician's records do not indicate that she experienced any adverse reaction. Patterson Decl. Ex. A ("Patterson Decl." refers to a declaration submitted by Collagen in support of summary judgment). Respondent claims, however, that subsequent to her treatment she developed an autoimmune disease and that Zyderm caused this disease. In 1988, she and her husband brought suit against Collagen in the United States District Court for the Northern District of California, seeking compensatory and punitive damages on counts of negligence, strict liability, breach of warranty, battery, conspiracy, and loss of consortium. Jurisdiction rested on 28 U.S.C. § 1332.

The district court granted summary judgment for Collagen on the ground that the Kennedys had failed to adduce any evidence supporting their claim that Zyderm had caused the autoimmune disease. App., *infra*, pp. 33a-37a. The Ninth Circuit originally affirmed, agreeing that the Kennedys "had failed to present sufficient evidence of causation to survive summary judgment," noting that their "expert affidavits on causation . . . were either speculative, highly equivocal, or both." App., *infra*, p. 32a. On rehearing, however, the court reversed, reasoning that under California law such speculative testimony "was sufficient to establish the existence of a genuine issue of material fact regarding causation." App., *infra*, p. 24a. This Court denied Collagen's petition for a writ of certiorari. 113 S. Ct. 3037 (1993).

On remand, the district court granted summary judgment for Collagen on the ground that the Kennedys'

common law claims were precluded by the MDA preemption statute, 21 U.S.C. § 360k(a). App., *infra*, pp. 20a-21a. That statute bars the states from imposing any requirement with respect to a medical device "(1) which is different from, or in addition to, any requirement applicable under [the MDA] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the MDA]." The district court pointed out that the First Circuit in *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993), and the Fifth Circuit in *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993), already had held that this statute bars common law claims relating to Zyderm similar to those asserted by the Kennedys. Hearing Tr. 12-13 ("Hearing Tr." refers to the transcript of the summary judgment hearing).

The Ninth Circuit reversed. The court's opinion invoked two separate grounds for decision. *First*, the court held that state common law does not impose a "requirement" within the meaning of the MDA preemption statute. In reaching this conclusion, the court extrapolated from an FDA regulation, 21 C.F.R. § 808.1(d)(1), which provides that the statute "does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices." The court asserted that "state common law is a law of general applicability and therefore cannot qualify as a *specific* requirement which may be preempted by the MDA." App., *infra*, p. 12a (emphasis in original). The Ninth Circuit rejected, as inadequately reasoned, the contrary decisions of the First Circuit in *King*, the Third Circuit in *Michael v. Shiley, Inc.*, 46 F.3d 1316 (3d

Cir.), *cert. denied*, 116 S. Ct. 67 (1995), the Fifth Circuit in *Stamps*, and the Eighth Circuit in *Martello v. CIBA Vision Corp.*, 42 F. 1167 (8th Cir. 1994), *cert. denied*, 115 S. Ct. 2614 (1995).

Second, the Ninth Circuit further opined, again rejecting the decisions of the other four circuits, that "it makes little sense to hold that the FDA's premarket approval process qualifies as a '*specific* requirement applicable to a *particular* device.'" App., *infra*, p. 12a (emphasis in original), quoting 21 C.F.R. § 808.1(d). The court continued, "[t]he fact that the premarket approval process involves specific requirements, *see* 21 C.F.R. § 814, 820, must not be confused with the premarket approval requirement itself acting as a *specific* requirement." *Id.* (emphasis in original). The court did not, however, explain why these observations were believed to be dispositive when the record established that the FDA in fact had imposed specific requirements on Zyderm pursuant to the PMA process. Moreover, the court ignored the fact that the very regulation upon which it relied expressly provides that state law is preempted when the FDA "has established specific counterpart regulations," 21 C.F.R. § 808.1(d), and the FDA itself has announced that "the counterpart FDA requirement [is] the requirement that the product have premarket approval." 43 Fed. Reg. 18661, 18664 (1978).

REASONS FOR GRANTING THE PETITION

The Ninth Circuit's decision in this case sticks out like a sore thumb. It is contrary to the decisions of every other circuit that has had occasion to consider the MDA preemption statute. The resulting conflict should be resolved so that a uniform body of federal preemption rules will apply wherever manufacturers of medical devices like Collagen may be sued. This case is a peculiarly appropriate vehicle for the resolution of this conflict and for the determination of all major and recurring preemption issues relating to Class III medical devices that the

FDA has found to be safe and effective and has approved for marketing pursuant to the rigorous and comprehensive PMA process.

1. The first general preemption issue decided below—whether state common law imposes "requirements" within the meaning of the MDA preemption statute—is one that arises in connection with every Class III medical device. Ten circuits now have considered this issue. The First, Second, Third, Fourth, Fifth, Sixth, Seventh, Eighth, and Eleventh Circuits all have held that state common law does impose "requirements" and thus is subject to preemption under the statute. *See, e.g. Mendes v. Medtronic, Inc.*, 18 F.3d 13, 16 (1st Cir. 1994); *Becker v. Optical Radiation Corp.*, 66 F.3d 18, 20 (2d Cir. 1995); *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 542 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994); *Duvall v. Bristol-Meyers-Squibb Co.*, 65 F.3d 392, 397-98 (4th Cir. 1995); *Reeves v. Acromed Corp.*, 44 F.3d 300, 304 (5th Cir.), *cert. denied*, 115 S. Ct. 2251 (1995); *Martin v. Telectronics Pacing Systems, Inc.*, 70 F.3d 39, 41 (6th Cir. 1995); *Mitchell v. Collagen Corp.*, 67 F.3d 1268, 1276 (7th Cir. 1995), *petition for cert. filed*, 64 U.S.L.W. 2288 (U.S. Feb. 20, 1996); *National Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988, 991 (8th Cir. 1994); *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1342 (11th Cir. 1995), *cert. granted* 116 S. Ct. 806 (January 19, 1996) (Nos. 95-754 and 95-886). Only the Ninth Circuit in this case has reached the contrary result. This Court presumably will resolve this conflict in *Medtronic*; but if for some reason it does not do so there, it should do so in this case.

2. The second general preemption issue decided below arises in connection with those Class III medical devices, like Zyderm, that the FDA has found to be safe and effective and has approved for marketing pursuant to the PMA process. Every other circuit that has considered the question—the First, Third, Fifth, Seventh, and Eighth

Circuits—has held that the requirements imposed by the FDA in connection with the PMA process indeed are "requirements" within the meaning of the MDA preemption statute and thus give rise to preemption. *See, e.g., King v. Collagen Corp.*, 983 F.2d 1130, 1134 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993); *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1324 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1421-22 (5th Cir.), cert. denied, 114 S. Ct. 86 (1995); *Mitchell v. Collagen Corp.*, 67 F.3d at 1276; *Martello v. Ciba Vision Corp.*, 42 F.3d 1167, 1169 (8th Cir. 1994), *cert. denied*, 115 S. Ct. 2614 (1995). Once again, the Ninth Circuit stands alone. The conflict created by the decision below on this issue also should be resolved, and the Court will not have occasion to consider this issue directly in *Medtronic*.

The Class III medical device in *Medtronic* was not found safe and effective or approved for marketing by the FDA pursuant to the PMA process. Instead, that device was granted premarket clearance under 21 U.S.C. 360(k) (the "510(k) process") upon a finding that it was "substantially equivalent" to a device already on the market. If this Court in *Medtronic* concludes that the more abbreviated 510(k) process imposes preemptive "requirements," then the same result for the PMA process should follow *a fortiori*. But if the Court does not so decide in *Medtronic*, the conflict created by the decision below will remain and should be resolved here.

The Ninth Circuit's holding on this issue is plainly incorrect. The comprehensive PMA process both encompasses and imposes requirements giving rise to preemption under the MDA preemption statute. The decision below to the contrary is based on a misreading of 21 C.F.R. § 808.1(d). That regulation provides that "state or local requirements are prempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act." The

Ninth Circuit apparently read the phrase "specific counterpart regulations" as referring solely to regulations specifically addressed to a particular device. That was wrong. As the FDA itself has explained, for Class III medical devices like Zyderm "the counterpart FDA requirement [is] the requirement that the product have premarket approval." 43 Fed. Reg. 18661, 18664 (1978). The FDA's own regulation, in other words, provides that the requirements imposed as a condition of obtaining premarket approval are preemptive under the MDA. In addition, the Ninth Circuit completely ignored the regulation's reference to "other specific requirements applicable to a particular device." As the facts of this case demonstrate, the marketing approval order generated by the PMA process imposes numerous such "specific requirements." See p. 6, *supra*. These requirements also are preemptive.

3. Because it erroneously held that state common law is never preempted and that the PMA process imposes no preemptive federal requirements, the Ninth Circuit did not consider the specific preemption issues relating to the Kennedys' common law claims of negligence, strict liability, breach of warranty, battery, and conspiracy decided in Collagen's favor by the district court. These issues are common in litigation of this sort and have been addressed by numerous courts of appeals. The circuits that have decided these issues are unanimous that claims of negligence, strict liability, and implied warranty all are barred by the MDA preemption statute. *See, e.g.*, *King*, 983 F.2d at 1135-36; *Michael*, 46 F.3d at 1324; *Stamps*, 984 F.2d at 1422; *Mitchell*, 67 F.3d at 1280, 1284; *Martello*, 42 F.3d at 1169. Such claims, like the Kennedys' additional claims of battery and conspiracy, all, at bottom, are claims that the medical device should have been designed, manufactured, packaged, labeled, and advertised in a manner different from that (1) explicitly approved by the FDA upon finding the device safe and effective and (2) explicitly required by the FDA

as a condition of continued marketability. The central purpose of the MDA preemption statute is to protect manufacturers of medical devices from conflicting demands of this sort.

The circuits disagree only with respect to claims of express warranty. The First and Sixth Circuits hold that such claims are preempted. *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 31 (1st Cir. 1995), *petition for cert. filed*, Feb. 16, 1996 (No. 95-1321); *Martin*, 70 F.3d at 42. The Third and Seventh Circuits hold that they are not. *Michael*, 46 F.3d at 1325; *Mitchell*, 67 F.3d at 1285. The Fourth Circuit holds that express warranty claims are preempted to the extent that they are based on FDA-mandated labeling, packaging, or advertising but are not preempted otherwise. *Duvall*, 65 F.3d at 400. The express warranty claim in this case is typical and may serve as an appropriate basis for resolving this disagreement.

The Kennedys allege that Collagen (presumably through its labeling and promotional materials, although the Kennedys eschew specificity) expressly warranted that Zyderm "would not cause injury" whereas "[i]n truth and fact, said product was unfit for human use." Complaint, p. 6. Even putting aside the factual question whether Collagen made a statement similar to that alleged, to prevail on their claim the Kennedys would have to persuade a court or jury to find that Zyderm in fact is not safe. Such a finding would directly contradict the FDA's explicit determination that Zyderm is safe and effective. Positing liability on that ground, moreover, would impose a state-law based requirement that Collagen change its manufacturing or other processes so as to make Zyderm "safe" by state-law standards. It would, in other words, impose state requirements different from, or in addition to, the federal requirements imposed under the MDA. That result is expressly prohibited by the MDA preemption statute.

This case provides a more suitable vehicle than either *Mitchell* or *Talbott* for deciding these specific preemption

issues. In *Mitchell*, the Seventh Circuit rejected express warranty claims on evidentiary grounds that are likely to preclude this Court's consideration of the specific preemption issue relating to that claim. *See Mitchell v. Collagen Corp.*, No. 95-1323 (S. Ct.), br. in response to pet. at 11, 14. The petition in *Talbott*, on the other hand, does not squarely raise these specific preemption issues but instead asks the Court to decide an idiosyncratic issue, not presented by any other case, concerning the implications for preemption of a criminal violation of federal law. *See Talbott v. C.R. Bard, Inc.*, No. 95-1321 (S. Ct.), br. in opp. at 9. In contrast, this case presents the full range of preemption issues that typically arise in litigation under the MDA.

4. Preemption of common law claims such as those asserted by the Kennedys not only follows from the statutory text, it furthers the congressional purpose. Preemption was designed in large part to protect the integrity of the PMA process. A PMA approval order constitutes the FDA's determination, following a lengthy and careful review process, that the approved medical device is safe and effective when manufactured, distributed, and sold in accordance with the conditions set forth therein. The approval order grants the manufacturer of the approved device a license to market the device strictly in accordance with conditions specified by the FDA to ensure safety and effectiveness. In turn, the MDA preemption statute means that the manufacturer may operate under this license free of conflicting or additional demands that might otherwise be imposed under state law. In this way, the states are prevented from second-guessing or undermining PMA approval orders.

Congress thereby has struck a balance that avoids both under-regulation and over-regulation. This was by express design. Congress developed the MDA as

> a balanced regulatory proposal intended to assure that the public is protected from unsafe and ineffective medical devices, that health professionals have

> more confidence in the devices they use or prescribe, and that innovations in the medical device industry are not stifled by unnecessary restrictions.

H.R. Rep. No. 853, 94th Cong. 2d Sess. 12 (1976). Congress intended preemption to play a vital role in achieving this balance.

Congress was fully aware of "the importance of the small innovative manufacturer [like Collagen] in the invention and development of new medical devices and the inability of these firms, because of limited financial resources, to sustain the high level of administrative costs demanded of a highly regulated industry." S. Rep. No. 33, 94th Cong., 1st Sess. 18 (1976). Congress determined that extraordinarily extensive federal oversight is necessary to ensure the safety and effectiveness of newly developed medical devices. But Congress further concluded that an additional layer of state-law requirements would be both unnecessary and counterproductive, noting that "interstate commerce would be unduly burdened" by the imposition of "differing requirements applicable to a medical device . . . by jurisdictions other than the Federal government." H.R. Rep. No. 853 at 45.

The broadly worded MDA preemption statute grew out of these concerns. It ensures that firms like Collagen, which have met the burden of demonstrating safety and effectiveness under the PMA process, will be subject only to those regulatory requirements that Congress and the FDA have chosen to prescribe. The decision below ignores and overrides this deliberate and purposeful congressional choice.

CONCLUSION

The petition should be held pending disposition of *Medtronic*; it should then be granted to the extent that the preemption issues it raises are left unresolved by the Court's decision in that case.

Respectfully submitted,

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APPENDICES

APPENDICES

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 94-15197

D.C. No. CV-89-02331-CAL

CHARLOTTE KENNEDY and ROBERT L. KENNEDY,
Plaintiffs-Appellants,

v.

COLLAGEN CORPORATION,
Defendant-Appellee.

Appeal from the United States District Court
for the Northern District of California
Charles A. Legge, District Judge, Presiding

Argued and Submitted
August 8, 1995—Pasadena, California

Filed October 17, 1995

Before: Warren J. Ferguson, Stephen Reinhardt
and David R. Thompson, Circuit Judges.

Opinion by Judge Ferguson;
Concurrence by Judge Reinhardt

OPINION

FERGUSON, Circuit Judge:

In this appeal, Charlotte and Robert Kennedy challenge the district court's grant of summary judgment in favor of defendant, Collagen Corporation ("Collagen"). The Kennedys contend that their state common law claims are not preempted by the Medical Device Amendments of 1976 ("the MDA"), 21 U.S.C. §§ 360c-360l (Supp. 1995), and that genuine issues of material fact remain in issue in their suit against Collagen. We reverse the district court and remand for trial.

I. BACKGROUND

This action arises out of Charlotte Kennedy's treatment with Zyderm Collagen Implant ("Zyderm"), a prescription medical product manufactured by defendant Collagen. Zyderm is used by physicians to treat soft tissue defects of the skin caused by disease, trauma, congenital defects, or aging. Following Charlotte Kennedy's treatment with Zyderm, she developed systemic lupus erythematosus ("SLE"), an autoimmune disease.

Upon contracting SLE, Charlotte and Robert Kennedy brought suit against Collagen alleging negligence, strict liability, breach of warranty, battery, conspiracy and loss of consortium. Based on the Kennedy's failure to present sufficient evidence of causation, the district court granted Collagen's original motion for summary judgment. This Court affirmed the decision of the district court in June 1992, but later granted the Kennedys' petition for rehearing, withdrew its earlier decision and reversed the district court. *Kennedy v. Collagen*, 967 F.2d 587 (9th Cir. 1992), *withdrawn*, 974 F.2d 1342 (9th Cir. 1992), *cert. denied*, —— U.S. ——, 113 S.Ct. 3037 (1993).

The present appeal stems from Collagen's motion for summary judgment filed on remand to the district court.

In its second motion for summary judgment, Collagen asserts that all of the Kennedys' claims are preempted by the MDA, 21 U.S.C. § 360k(a). The district court granted Collagen's motion, finding that the Kennedys' claims are preempted under § 360k(a). This appeal timely followed.

On appeal, the Kennedys make two arguments. First, they contend that § 360k(a) only preempts state law to the extent that state law establishes additional or divergent requirements for a *particular* medical device. Because neither the state common law nor the FDA has established any *specific* requirements unique to Zyderm, the Kennedys assert, their state common law claims are not preempted. In addition, the Kennedys assert that the state common law, pursuant to which they are suing, is a law of general applicability and therefore specifically not preempted by the MDA.

II. DISCUSSION

I. *Standard of Review*

This court reviews the district court's grant of summary judgment on a pure question of law, in which there are no disputed facts, *de novo*. *Turner v. Prod*, 707 F.2d 1109, 1114 (9th Cir. 1983).

II. *History of The MDA*

The MDA was enacted largely in response to the public outcry following the injuries suffered in the 1960s and early 1970s by women using the Dalkon Shield contraceptive device. *See Ministry of Health v. Shiley*, 858 F. Supp. 1426, 1434 (C.D. Cal. 1994). Federal investigations in the wake of the Dalkon Shield injuries confirmed that the "pace of the [medical device] industry far exceeded the FDA's ability to control it." *Id.* at 1434 (quoting Susan Barlett Foote, *Loops and Loopholes: Hazardous Device Regulation Under the 1976 Medical*

Device Amendments to the Food, Drug and Cosmetic Act, 7 ECOLOGY L.Q. 101, 102-103 (1978)).

Congress subsequently passed the MDA in order "to assure the reasonable safety and effectiveness of medical devices intended for human use." H.Conf.Rep. No. 1090, 94th Cong., 2d Sess. *reprinted in* 1976 U.S. Code Cong. & Admin. News 1070, 1103. The MDA gives the FDA broad powers to classify and regulate medical devices. Under the MDA, the FDA must assign a medical device to one of three statutorily delineated categories. Class I devices are those devices which pose little or no threat to public health. They are subject to only general requirements concerned with their manufacture. Tongue depressors are one example of a Class I medical device. *See* 21 U.S.C. § 360c(a)(1)(A); 21 C.F.R. § 860.3(c)(1). Class II devices include items such as tampons and oxygen masks. Use of Class II devices involves some risk of injury and, as a result, the FDA establishes performance standards, postmarket surveillance programs and guidelines for their use. *See* 21 U.S.C. § 360c(a)(1)(B); 21 C.F.R. § 860.3(c)(2).

Class III devices are those devices which are implanted in the body or which pose a potentially unreasonable risk of injury. *See* 21 U.S.C. § 360c(a)(1)(C); 21 C.F.R. § 860.3(c)(3). They include Zyderm, as well as pacemakers, heart valves and replacement joints. Because of their inherent dangerousness, Class III devices are subject to the most stringent FDA regulation. All Class III devices are required to obtain premarket approval prior to being released for sale and use. 21 U.S.C. § 360e; 21 C.F.R. § 814.1(c).

In order to attain premarket approval, the manufacturer of a Class III device must submit all of its information on any investigations concerning the device's safety or effectiveness, a statement of the intended use of the product, a description of the expected manufacturing process, and any other requested information to the FDA.

21 U.S.C. §§ 360e(c)(1)(A)-(G); 21 C.F.R. §§ 814.20 (b)(2)-(12). Prior to approval by the FDA, the existence of an application for approval may not be publicly disclosed unless it has previously been publicly disclosed or acknowledged. 21 C.F.R. § 814.9(b). There is no opportunity for public comment or for any public challenge to the information presented to the FDA by the device manufacturer.

III. GENERAL PREEMPTION PRINCIPLES

The principle of federal preemption of state law derives from Article VI of the Constitution, the Supremacy Clause. Article VI establishes the laws of the United States as "the supreme Law of the Land . . . any Thing in the constitution or Laws of any state to the Contrary notwithstanding." Art. VI, cl. 2.

Federal law can preempt state law in one of two ways. Congress may either explicitly state its intent to preempt state law in the language of a statute or Congress may imply its intent to preempt through the structure and purpose of a statute. *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). Implicit preemption can itself take two forms. Congress may either occupy a field by passing a statutory scheme so extensive that it covers an entire legislative field or Congress may enact a federal law which makes compliance with a state law impossible. *Fidelity Federal Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982).

Where Congress has made its intent to preempt explicit in a statute, the Supreme Court has held that:

> 'there is no need to infer congressional intent to preempt state laws from the substantive provisions' of the legislation . . . Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not preempted.

Cipollone v. Liggett Group, Inc., —— U.S. —— 112 S.Ct. 2608, 2618 (1992) (citations omitted). Therefore, the question to be answered in instances of express preemption is the *extent* to which Congress intended to preempt state law.

Regardless of the form preemption takes, the Supreme Court has consistently imposed a strong presumption against preemption.

> Consideration of issues arising under the Supremacy Clause 'start with the assumption that the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress.'

Cipollone, 112 S.Ct. at 2617 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). In its most recent decision on preemption, the Supreme Court held that the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 et seq. (1988 ed. and Supp. V), did not preempt a New York law requiring hospitals to add "surcharges on bills of patients whose commercial insurance coverage is purchased by employee health-care plans governed by ERISA, and [requiring] . . . surcharges on HMOs, insofar as their membership fees are paid by an ERISA plan." *N.Y. Conference of Blue Cross v. Travelers Ins.*, —— U.S. ——, 115 S.Ct. 1671, 1673-74 (1995). In *N.Y. Conference*, the Court reaffirmed that even a preemption provision in an expansive statutory scheme such as ERISA must be read narrowly, especially in areas of historic state concern such as health and safety. *Id.* at 1676.

Similarly, in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), the Court applied the presumptions against preemption to uphold a state punitive damage award in the face of comprehensive federal legislation addressing nuclear safety. In *Silkwood*, the Court noted the tension its holding created between federal legislation to regulate

nuclear safety and a state's ability to impose its own laws of liability; however, the Court was reluctant to find complete preemption in the face of congressional silence with regard to tort remedies. "It is difficult to believe that Congress would, without comment, remove all means of recourse for those injured by illegal conduct." *Silkwood*, 464 U.S. at 251.

IV. PREEMPTION UNDER THE MDA

Congress explicitly provided for the preemption of state law under the MDA. Section 360k(a) establishes that:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
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> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
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> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). Some courts have read the language as creating an expansive federal preemption of state law. The Eighth Circuit, for example, has read the language of § 360k(a) to preempt *any* state tort claims dealing with safety, effectiveness or any other aspect governed by the FDA's pre-market approval process.[1] *Martello v. CIBA Vision Corp.*, 42 F.3d 1167, 1169 (8th Cir. 1994).

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[1] In *Anguiano v. E.I. Du Pont De Nemours & Co., Inc.*, 44 F.3d 806. (9th Cir. 1995), we held that state tort law was not preempted with respect to the Class II device in question. *Id.* at 810. Our reason was that there were no federal requirements applicable to the device. *Id.* In dictum, we expressed the view that in promulgating the MDA, Congress intended to preempt state tort law. *Id.* at 809. It is obvious from what we held in *Anguiano* that the dictum was either overbroad or not intended to be taken literally. In any event, upon careful analysis, we believe that the dictum was not correct.

However, the statutory language of § 360k(a) does not create the broad, sweeping preemption found by the Eighth Circuit. Reading § 360k(a)(1) broadly requires recognizing that *any* state law is, by definition, a law "in addition to" federal law. A broad reading of § 360k(a) thus renders the "different from" language meaningless and forces a strained reading of the statute. Similarly, in *N.Y. Conference*, the Supreme Court held that the term "relate[s] to" is potentially unbounded if interpreted broadly. If it "were taken to extend to the furthest stretch of its indeterminacy, then for all practical purposes pre-emption would never run is course, for '[r]eally, universally, relations stop nowhere.' " *N.Y. Conference*, 115 S.Ct. at 1677 (citations omitted). Therefore, the Court held that in order to define "relate[s] to" in a meaningful manner, a court must look to the purpose and effects of the state law in issue. *Id.* at 1676.

We must address two threshold questions: (1) what constitutes a "State . . . requirement" and (2) what constitutes a "requirement" under the MDA. *Lohr v. Medtronic*, 56 F.3d 1335, 1342 (11th Cir. 1995). Congress has not addressed these precise questions. Therefore, we must look to the FDA's understanding of the scope of the MDA's statutory preemption provision since the FDA is the agency charged by Congress with implementing the MDA. An agency's interpretation of its own statute is controlling so long as not contrary to Congress' intent. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844 (1984). As long as the FDA has propounded any "reasonable interpretation" of the provision, this Court has no cause to overturn the agency's interpretation in favor of its own. *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945).

The FDA interprets § 360k(a) in 21 C.F.R. § 808.1(d). Section 808.1(d) provides:

> State or local requirements are preempted *only* when the Food and Drug Administration has established

> *specific* counterpart regulations or there are other *specific* requirements applicable to a *particular* device under the act, thereby making any existing divergent State or local requirements applicable to the device different from or in addition to, the *specific* Food and Drug Administration requirements . . .

21 C.F.R. § 808.1(d) (emphasis added). Section 808.1(d) goes on to delineate other state and local requirements which affect medical devices, but which are not preempted by § 360k(a):

> (1) Section 521(a) does not preempt State or local requirements of *general applicability* where the purpose of the requirement relates either to other products in addition to devices . . . or to unfair trade practices in which the requirements are not limited to devices . . .
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> (6)(ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices . . .

21 C.F.R. § 808.1(d)(1)-(9) (emphasis added). Section 808.1(d) explicitly requires that state or local requirements *only* be preempted where there exist *specific* counterpart requirements or regulations applicable to a *particular* device.

Defendants contend and the district court agreed that the premarket approval process required by the FDA for Class III devices constitutes a *specific* federal requirement which preempts state common law claims. Other courts addressing the question of the preemptive scope of the MDA have devoted considerable analysis to the issue of whether the premarket approval process is specific enough to satisfy the FDA's narrow preemption rule. *See e.g., Martello*, 42 F.3d at 1169; *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1421-22 (5th Cir.), *cert. denied*, —— U.S. ——, 114 S.Ct. 86 (1993). Courts have also expostulated on whether state common law claims are of spe-

cific enough applicability to escape the FDA's pronouncement that laws of general applicability are not preempted. *See e.g., Michael v. Shiley*, 46 F.3d 1316, 1323 (3rd Cir. 1995); *King v. Collagen Corp.*, 983 F.2d 1130, 1136 (1st Cir.), *cert. denied*, —— U.S. ——, 114 S. Ct. 84 (1993).

While most courts have found that at least some, if not all, state common law claims are preempted by the MDA, these courts have failed to devote any attention to the meaning of "general applicability" within the context of the MDA and its accompanying regulations. They have also failed to consider the question of whether Class III devices as a group can constitute a "*particular* device" within the FDA's understanding of that term. *See e.g., King*, 983 F.2d at 1139; *Stamps*, 984 F.2d at 1420-21; *Martello*, 42 F.3d at 1169. In addition, these courts have ignored the existence of other regulations promulgated by the FDA like § 808.1(d)(6)(ii) which specifically provides that a state or local requirement prohibiting the manufacture of adulterated or misbranded devices, a subject of the FDA premarket approval process, is not preempted unless it is interpreted or enforced by the state or local government in such a manner as to create a "substantive requirement for a *specific* device." 21 C.F.R. § 808.1(d)(6)(ii).

The reasoning of courts which have found that the premarket approval process preempts state law claims stands in sharp contrast to the analysis of Class II devices. In Class II cases courts have consistently focussed both on the specificity of the federal requirement and the particularity of the device. For example, in *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243,246 (5th Cir.), *reh'g denied*, 873 F.2d 297 (1989), the court refused to preempt state laws relating to the design, construction, and composition of tampons because the only federal regulations applying to tampons, as a *particular* device, were labeling and warning requirements. *See also Anguiano v. E.I. DuPont*

de Nemours & Co., 44 F.3d 806, 810 (9th Cir. 1995) (holding that "[b]ecause the FDA ha[d] not promulgated specific regulations regarding [the product], the MDA [did] not preempt Anguiano's state law claims"). Thus, other courts have required less overall specificity under § 808.1(d) for Class III devices than for Class II devices. They have required particularity in the preemption analysis of Class II devices, but have ignored the word "particular" in the preemption analysis of Class III devices.

Such distinctions between Class II and Class III devices make little sense.[2] Congress enacted the MDA to ensure that safe and effective medical devices were introduced into the market. H.R. Conf. Rep. No. 1090. There is no reason for a court's preemption analysis to change depending on the class of device in issue. In implementing the MDA, the FDA has explicitly interpreted § 360k(a) to exempt certain state laws which affect medical devices. As long as the FDA's interpretation of the MDA's preemption provision does not contravene congressional intent, the FDA's interpretation is controlling. *Chevron*, 467 U.S. at 844.

Section 808.1(d)(1) provides that the MDA does not preempt laws of general applicability. State common law is a law of general applicability. Although specific state common laws may have come into existence in response to a harm created by a particular device, state common law does not relate solely to or regulate any *particular* device or product to the exclusion of other devices or

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[2] Other courts have suggested that preemption is more applicable to Class III devices because the level of regulatory control is greater for Class III devices than far Class II devices. *See, e.g., Martello* 42 F.3d at 1168. While it is true that Class II devices are subject to specific performance standards only *if* the FDA deems them a sufficient health hazard whereas all Class III devices are subjected to a stringent "premarket approval process," this distinction in no way changes the fact that the MDA does not preempt claims based upon state common law of general applicability.

products. Courts which have found state common law actions to be preempted have generally relied on the Supreme Court plurality's conclusion in *Cipollone* that state common law can exert a regulatory effect on business. *Cipollone*, 112 S.Ct. at 2620 (citing *San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 247 (1959)). *See e.g. Stamps*, 984 F.2d at 1422; *King*, 983 F.2d at 1134 (citing *San Diego Building Trades*).

However, the fact that state common law *may* have an indirect regulatory effect is not dispositive as to whether it qualifies as a *specific* requirement applicable to a *particular* device. Unlike positive state enactments, common law imposes only an indirect effect on manufacturers. Defendants in common law damages actions retain the freedom to choose their own response to the legal challenges they face. For example, manufacturers facing common law challenges retain the discretion whether to alter their product or whether to bear the cost of any law suits that might result from their decision, whereas, manufacturers bound by positive state enactments are required to conform their product to the law. *See Cipollone*, 112 S.Ct. at 2627 (Blackmun, J., dissenting). The potential for state comon law to create an indirect regulatory effect is insufficient to alter the fact that state common law is a law of general applicability and therefore cannot qualify as a *specific* requirement which may be preempted by the MDA.

In addition, it makes little sense to hold that the FDA's premarket approval process qualifies as a "*specific* requirement applicable to a *particular* device." 21 C.F.R. § 808.1(d) (emphasis added). *All* Class III devices are required to obtain premarket approval before being sold in interstate commerce. 21 U.S.C. § 360e; 21 C.F.R. § 814.1. The fact that the premarket approval process involves specific requirements, *see* 21 C.F.R. § 814, 820, must not be confused with the premarket approval requirement itself acting as a *specific* requirement. The

result of holding that the premarket approval process is a "specific requirement applicable to a particular device" is the preemption of claims which, if barred, leave injured plaintiffs without any remedy in state or federal law. *See Michael*, 46 F.3d at 1320 (noting that the MDA does not oblige any Class III manufacturer or distributor to compensate a person injured by a Class III device for their medical expenses or their pain and suffering).

As the Supreme Court held in *Silkwood*, it is incredible to believe that Congress would, without comment, void all means of relief for those injured by illegal conduct. *Silkwood*, 464 U.S. at 251. State common law damages actions guarantee people who are injured by a manufacturer the opportunity to be compensated for their harm. State regulation of manufacturers directly governs their actions in releasing their goods into the market. Thus, state common law serves a different purpose than state regulation and is unlikely to have been the target of congressional attempts to promote the introduction of safe medical devices onto the market or even to curb dual regulation of the medical devices industry. Reading the MDA's preemption provision in the manner advocated by the defendant would result in consumers of Class III devices being left without recourse for any harm suffered. Such a result flies in the face of the congressional intent behind the MDA legislation: consumer protection, 43 Fed. Reg. 18,663 (May 2, 1978).

The federal law requiring the premarket approval of Class III devices was not enacted in order to free manufacturers from the everyday burdens of the marketplace after they are permitted to enter it. Premarket approval is supposed to benefit consumers, not create a rose garden, free from liability, for manufacturers. Courts which have held to the contrary have done so in contravention of the FDA's regulations and statements concerning the preemptive scope of the MDA. The FDA's determination that § 360k(a) must be read narrowly establishes a plaus-

ible interpretation of the statute and comports with the congressional intent behind the legislation. Absent a compelling reason to overturn the FDA's interpretation of the legislation, we must adopt that interpretation and reverse the district court's grant of summary judgment.

REVERSED AND REMANDED.

REINHARDT, Circuit Judge, concurring:

I join fully in Judge Ferguson's opinion for the court. I write separately to clarify further the meaning of the word "requirement" as it is used in 21 U.S.C. § 360k(a). The Medical Device Amendments of 1976 (the "MDA") preemption provision states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any *requirement*—
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> (1) which is different from, or in addition to, any *requirement* applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a *requirement* applicable to the device under this chapter.

21 U.S.C. § 360k(a).

The first reference to "requirement" is to requirements imposed by state or local entities, while the second and third references are to federal requirements imposed under the MDA. It is the meaning of the first "requirement"—state or local requirements applicable to medical devices—that is at issue here.[1]

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[1] The Eleventh Circuit erroneously suggests that this court understands the first reference to "requirement" to include general state tort law. *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1342 (11th Cir. 1995). The *Lohr* court's suggestion is based on dicta in *Anguiano v. E.I. Du Pont De Nemours & Co.*, 44 F.3d 806, 809 (9th Cir. 1995). In *Anguiano*, we actually considered the second and third references to "requirement" (the federal references) in § 306k(a), and held that the plaintiffs' state claims were not preempted. We concluded that the *federal* controls applicable to the Class II device in question were too insubstantial to constitute a "requirement" under the MDA. *Id.* at 810. Class III devices were not at issue in that case and our speculation as to how Class III devices might be treated under the statute was just that—speculation. So, too, were any observations regarding the scope or preemptive effect of the *first* reference to "requirement," the requirement at issue here.

Some courts have concluded that the term "requirement" as it relates to state or local regulation includes state common law of general applicability. These courts have either accepted that view without explanation, relied on a proposition endorsed in a different context by only a plurality of the Supreme Court in *Cipollone v. Liggett Group, Inc.*, 112 S.Ct. 2608 (1992), or read 21 C.F.R. § 808.1(b) in isolation from the rest of § 808.1.[2] As discussed in Judge Ferguson's opinion for the court, the dicta and occasional holdings of the courts that have concluded that MDA preempts state common law ignore the controlling interpretation of § 360k(a) adopted by the FDA, the federal agency charged with implementing the Medical Device Amendments.

The term "requirement" is not self-defining, and Congress did not provide any definition of the term as it is used in relation to the actions of a state (the first reference) or in relation to federal actions (the second and third references). Rather, Congress left to the FDA the task of adopting implementing regulations defining "requirement," and explaining the operation of other provisions of the MDA. The controlling interpretations of the term "requirement" are found in 21 C.F.R. § 808.1. Read in its entirety, section 808.1 clearly provides that

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[2] See, *e.g.*, *Gile v. Optical Radiation Corp.*, 22 F.2d 540, 542 (3rd Cir.), *cert. denied*, 115 S.Ct. 429 (1994) (declaring that the Supreme Court has clearly stated that the word "requirement," in the context of an express preemption provision, includes state law claims); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1333 (7th Cir.), *cert. denied*, 113 S.Ct. 327 (1992) (suggesting in dicta that § 360k(a) preempts state common law decisions); *Martello v. CIBA Vision Corp.*, 42 F.3d 1167, 1168 (8th Cir. 1994), *cert. denied*, 115 S.Ct. 2614 (1995) (relying on phrase "whether established by statute, ordinance, regulation, or court decision" in 21 C.F.R. § 808.1(b) to conclude preemption extends to state tort actions); *Lohr*, 56 F.3d at 1342 (adopting the Seventh Circuit's reasoning and relying on the conclusions of other circuits that common law actions are state requirements within the meaning of § 360k(a)).

§ 306k(a) preempts only state and local requirements the terms of which are *specifically* "applicable to medical devices," and that it does *not* preempt state and local requirements "of general applicability;" i.e., state and local requirements the purpose of which relates "to other products in addition to [medical] devices." 21 C.F.R. § 808.1(a); 21 C.F.R. § 808.1(d)(1). In other words, the FDA's implementing regulations define and limit the term (state) "requirement." Under those regulations, what is preempted by the MDA are state and local *medical device* requirements, not state and local general laws, whether tort or contract, common or statutory. 21 C.F.R. § 808.1(d)(1). In short, § 808.1 makes it clear that general state tort law is *not* preempted by the MDA.

A few courts have pointed to the inclusion of the term "court decisions" in 21 C.F.R. §808.1(b) as evidence that state tort law claims are generally preempted. *See, e.g., Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 n.3 (3rd Cir.), *cert. denied*, 115 S.Ct. 429 (1994). They argue that the inclusion of "court decisions" demonstrates that all state common law is preempted. The argument is a non sequitur. The court decisions that are preempted are only those that involve state requirements of specific rather than general applicability. The fact that a court decision involves a medical device is not determinative of whether that court decision constitutes a preempted state requirement; what is determinative is whether the court decision implements a principle of general tort law or is based on a rule or regulation aimed specifically at medical devices. A contrary interpretation would bring § 808.1(b) into direct conflict with § 808.1(d)(1). There is no reason for such a conflict, since the two provisions, read in context, can easily be reconciled.[8]

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[8] Appellate courts have generally ignored 21 C.F.R. § 808.1(d)(1). Only a few circuit courts even bother to mention the subsection. *See Michael v. Shiley, Inc.*, 46 F.3d 1316, 1323 n.4 (3rd Cir. 1995) (noting plaintiff's argument based on the "general applicability"

Section 808.1(b) sets forth the "general rule" that states may not establish or maintain "requirements" with respect to medical devices that differ from the federal rules governing these devices. As noted *supra*, the term "requirement" is defined as including "court decisions." We can assume for purposes of this decision that were we to read § 808.1(b) in isolation, there might be some ambiguity with respect to the latter term, and that it could be read to refer either to all court decisions or only to those court decisions that adopt special rules applicable to medical devices. However, when read together with § 808.1(d)(1), any ambiguity disappears.

In § 808.1(d)(1), which, of course, appears *after* § 808.1(b), the scope of the earlier section is expressly clarified and limited. Section 808.1(d)(1) specifically provides that "requirements" involving laws of general applicability, are *not* preempted. Since, under § 808.1(b), "requirements" includes "court decisions," "court decisions" must be read as *not* including decisions involving rules of general applicability. Any other reading would

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language in § 808.1(d)(1) but expressing no view on the effect of § 808.1(d)(1) "because Shiley disclaimed all implied warranties as it was entitled to do under the Code"); *Gile*, 22 F.3d at 543 n.2 (ignoring the "general applicability" language and seemingly relying on the fact that neither the phrases "state tort claim" nor "common law claim" are listed in 21 C.F.R. § 808.1(d)); *King v. Collagen Corp.*, 983 F.2d 1130, 1139 (1st Cir.), *cert. denied*, 114 S.Ct. 84 (1993) (Aldrich, J., concurring) (offering the proposition that "When a statute is clear the agency interpretation must give way" as explanation for why § 808.1(d)(1) does not conflict with the court's decision). District courts have addressed § 808.1(d)(1) more often than appellate courts with varied conclusions. *Compare Mitchell v. Collagen Corp.*, 870 F.Supp. 885 (N.D. Ind. 1994) (rejecting plaintiffs contention, based upon § 808.1(d), "that state tort laws of general applicability (i.e., not applicable only to medical devices) are not preempted") with *Ministry of Health v. Shiley*, 858 F.Supp. 1426, 1435 (C.D. Cal. 1994) (relying on the "general applicability" language of § 808.1(d)(1) and Advisory Opinions issued by the Office of the Chief Counsel for the FDA to conclude state tort claims are not subject to blanket preemption).

make the scope of the term "court decisions" far broader than, and entirely inconsistent with, the other terms (i.e. statute, ordinance, and regulation) which are included within the definition of "requirement." In short, the inclusion of the term "court decision" in § 808.1(b) cannot serve to modify the provision in § 808.1(d) that limits the term "requirements" to those provisions applicable expressly to medical devices. If for no other reason than the order in which they appear, its is § 808.1(d) that specifically limits and explains the scope of the term "court decision," as used in § 808.1(b), not vice-versa.

To summarize, if a state common law requirement is not specifically directed at medical devices, but affects such devices in the same manner as it affects all other products, a claim based upon that state law requirement is not preempted. Accordingly, generally applicable state common law, including tort law, is not preempted by § 360k(a).

APPENDIX B

[Filed Jan. 18, 1994]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

No. C89-2331-CAL

CHARLOTTE KENNEDY, *et al.*,
Plaintiffs,

v.

COLLAGEN CORPORATION,
Defendant.

ORDER GRANTING MOTION
FOR SUMMARY JUDGMENT

Defendant Collagen Corporation's motion for summary judgment came on for regularly noticed hearing on December 17, 1993, the Honorable Charles A. Legge, District Judge, presiding. Kathleen D. Patterson of Sedgwick, Detert, Moran & Arnold, and Joe W. Redden, Jr., of Beck, Redden & Secrest, appeared as counsel on behalf of defendant, Collagen Corporation. Michael M. Essmyer, of Michael M. Essmyer & Associates, appeared on behalf of plaintiffs, Charlotte Kennedy and Robert Kennedy.

After full consideration of the evidence and points and authorities submitted by the parties, and oral arguments of counsel, it appears and the Court finds, for the reasons set forth by the Court on the record in open court, which record is hereby incorporated by reference, that plaintiffs' claims are preempted under 21 U.S.C. section 360k(a), that there is no genuine issue of material fact with respect thereto and, therefore, Collagen Corporation is entitled to judgment as a matter of law.

IT IS ORDERED THAT Collagen Corporation's motion for summary judgment is granted and judgment shall be ordered forthwith as requested in said motion in favor of Collagen Corporation and against Charlotte Kennedy and Robert Kennedy.

Dated: January 18, 1994

/s/ Charles A. Legge
CHARLES A. LEGGE
United States District Judge

APPENDIX C

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 91-15597

D.C. No. CV-89-02331-CAL

CHARLOTTE KENNEDY and ROBERT KENNEDY,
Plaintiffs-Appellants,

v.

COLLAGEN CORPORATION,
Defendant-Appellee.

Appeal from the United States District Court
for the Northern District of California
Charles A. Legge, District Judge, Presiding

Argued and Submitted May 15, 1992
San Francisco, California

MEMORANDUM*

(Filed Sept. 8, 1992)

BEFORE: FERGUSON, REINHARDT, and KOZINSKI, Circuit Judges.

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[1] **This disposition is not appropriate for publication and may not be cited to or by the courts of this circuit except as provided by 9th Cir. R. 36-3.**

This is a products liability case which ended with the granting of summary judgment for the defendant. We reverse.

The action arises from Charlotte Kennedy's treatment with Zyderm[R] Collagen Implant ("Zyderm"), a prescription medical product manufactured by defendant Collagen Corporation ("Collagen"). Zyderm is injected by a doctor into facial wrinkles for a smoother appearance. Kennedy claims to have developed systemic lupus erythematosus, an automimmune [sic] disease, as a result of this treatment.

Collagen filed a motion for summary judgment on the ground that the plaintiffs had failed to produce any evidence establishing a prima facie case of causation.

At the hearing on the motion, the plaintiffs submitted an affidavit executed by Dr. Joseph Spindler on the issue of causation. The district court concluded that neither the testimony of the plaintiffs' designated expert witnesses nor Dr. Spindler's affidavit raised a genuine issue of material fact on the issue of causation. In addition, the court denied the plaintiffs' motion to designate additional experts, including Dr. Spindler, because the motion was untimely.

The plaintiffs subsequently filed a motion for a new trial, which the court also denied.

We reverse. Dr. Spindler's affidavit established the existence of a genuine issue of material fact regarding causation and was sufficient to preclude summary judgment.

DISCUSSION

We review the district court's grant of summary judgment de novo. *State Farm Fire & Casualty Co. v. Martin*, 872 F.2d 319, 320 (9th Cir. 1989). We must determine viewing the evidence in the light most favorable to the nonmoving party, whether there are any genuine issues of material fact and whether the district court correctly

applied the relevant substantive law. *Tzung v. State Farm Fire & Casualty Co.*, 873 F.2d 1338, 1339-40 (9th Cir. 1989).

In moving for summary judgment, the defendant did not offer any testimony or affidavits of its own witnesses. Instead, it relied on the deposition testimony of the plaintiffs' experts, excluding of course Dr. Spindler's affidavit.

We confine our study of the record to Dr. Spindler's affidavit and do not determine the sufficiency of the deposition testimony of the plaintiffs' other medical experts.

Under California law, the Kennedys were required to prove causation "within a reasonable medical probability based upon competent expert testimony." *Jones v. Ortho Pharmaceutical Corp.*, 163 Cal. App. 3d 396, 402 (1985). Dr. Spindler's affidavit was such testimony and was sufficient to establish the existence of a genuine issue of material fact regarding causation. Dr. Spindler affirmed that "[b]ased on reasonable medical probability," the Zyderm injections caused Charlotte Kennedy's systemic immunological injuries. Dr. Spindler based his opinion on his examination of Kennedy; review of her medical history and records; numerous laboratory tests of Kennedy which showed a positive ANA, anti-histone antibody, and anticentromere antibody; and the temporal relationship between the injections and her condition. Accepted on its own terms, the affidavit demonstrated a "reasonable medical probability" that the defendant's conduct caused Kennedy's injuries.

The defendant contends that Dr. Spindler's use of language such as "suspect" and "could have been" rendered the affidavit insufficient to establish a "reasonable medical probability." We disagree.

California courts have held that words such as "speculative" and "conjecture" do not render a doctor's testimony speculative if, taken as a whole, the testimony

states the doctor's opinion of reasonable medical probability. *See Cullum v. Seifer*, 1 Cal. App. 3d 20, 26 (1969); *Gay v. Workers' Compensation Appeals Bd.*, 96 Cal. App. 3d 555, 564 (1979). In *Gay*, the plaintiff appealed a finding of the Workers' Compensation Appeals Board that apportioned 50 percent of his psychiatric disability as nonindustrial. The plaintiff attacked the opinion of the psychiatrist who had recommended apportionment and argued, *inter alia*, that the opinion could not support apportionment because it included the statement, "Whether any of the symptoms preexisted [the patient's] current employment is speculative since the patient denies it." The plaintiff contended that this statement showed that the psychiarist was improperly "speculating" about apportionment. The court disagreed, stating:

> In evaluating a medical report, isolated statements may be misleading. Intellectual candor of a physician may lead to single statements which, when isolated, may be misunderstood. In evaluating the evidentiary value of medical evidence, a physician's report and testimony must be considered as a whole rather than in segregated parts. Thus, the physician's entire report and testimony when considered a [sic] a whole, must demonstrate that, based upon reasonable medical probability, there is a legal basis for apportionment.

96 Cal. App. 3d at 564 (citations omitted).

In *Cullum*, a malpractice case, the court reviewed the testimony of an expert witness, a doctor, who testified on the issue of proximate cause. The court examined the totality of the doctor's testimony on the issue and concluded that even though the witness referred at one point to "conjecture," the testimony as a whole stated the doctor's opinion of reasonable medical probability. The court explained:

> The isolated characterization of 'conjecture' must be weighed as to its true meaning and significance in

> the light of the testimony which preceded it. . . . [T]he main object is not to draw fine distinctions based upon accurate definitions or words, but to ascertain the real idea expressed."

1 Cal. App. 3d at 26 (citations and internal quotation marks omitted). Here, Dr. Spindler's affidavit, read in its entirety, clearly stated his opinion of reasonable medical probability.

A jury was entitled to hear Dr. Spindler's testimony. *See Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1535 (D.C. Cir. 1984), *cert. denied*, 469 U.S. 1062 (1984). In *Ferebee*, where both sides presented expert opinion testimony on the issue of whether paraquat poisoning caused the plaintiff's pulmonary fibrosis, the D.C. Circuit held that the jury was entitled to decide the victor in the battle of experts. *Id.* The court distinguished between the standard for the admission of evidence based on novel scientific techniques or methodologies, where "the basis of that opinion must be shown to be generally accepted as reliable within the expert's particular scientific field," and the standard for "the admission of scientific opinion testimony that, while controversial in its conclusions, is based on well-founded methodologies." *Id.* (citations and internal quotation marks omitted). The court stated further:

> [A] cause-effect relationship need not be clearly established by animal or epidemiological studies before a doctor can testify that, in his opinion, such a relationship exists. As long as the basic methodology employed to reach such a conclusion is sound, such as use of tissue samples, standard tests, and patient examination, products liability law does not preclude recovery until a "statistically significant number of people have been injured or until science has had the time and resources to complete sophisticated laboratory studies of the chemical. In a courtroom, the test for allowing a plaintiff to recover in a tort suit of this type is not scientific certainty but legal suffi-

> ciency; if reasonable jurors *could* conclude from the expert testimony that paraquat more likely than not caused [the plaintiff's] injury, the fact that another jury might reach the opposite conclusion or that science would require more evidence before conclusively considering the causation question resolved is irrelevant. That [the plaintiff's] case may have been the first of its exact type, or that his doctors may have been the first alert enough to recognize such a case, does not mean that the testimony of those doctors, who are concededly well qualified in their fields, should not have been admitted.

Id. at 1535-36 (emphasis in original).

Here, the reliability of Dr. Spindler's methodology is not disputed. The district court was inaccurate in believing that Dr. Spindler's opinion was based primarily on the temporal relationship between the Zyderm injections and Kennedy's injuries and was not based on "any other laboratory test of plaintiff, epidemiological evidence, or toxicological evidence." Furthermore, the court was not presented with any facts demonstrating that Dr. Spindler's methodology differed from procedures generally accepted by authorities in the field of immunology.[1] "[I]n determining . . . whether the informational basis of an expert opinion is of a type reasonably relied upon by experts in the field, "[t]he proper inquiry is not what the court deems reliable, but what experts in the relevant discipline deem it to be." *In re Paoli Railroad Yard PCB Litigation*, 916 F.2d 829, 853 (3rd Cir. 1990), *cert. denied*, 111 S. Ct. 1584 (1991) (citations omitted).[2] *See*

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[1] Nor did Collagen contend that Dr. Spindler was not a competent medical expert.

[2] In *Paoli*, the Third Circuit reversed the district court's grant of summary judgment for defendants and held that the district court had failed to give reasons for excluding as unreliable the bulk of the expert testimony upon which the plaintiffs had relied to establish causation.

In the present case, it is unclear whether the district court found Dr. Spindler's affidavit inadmissible under Fed. R. Evid. 703, or

also id. at 856-58; *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3rd Cir. 1990) (reversing district court's grant of summary judgment for defendants; holding that the district court erred in failing to make a record-supported, factual finding that plaintiff's doctor relied upon data not regarded as reliable by experts in the field). Thus, the district court erred in concluding that Dr. Spindler's affidavit was insufficient to preclude summary judgment.

In closing, we note that *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 951 F.2d 1128 (9th Cir. 1991), and other Bendectin cases are distinguishable. In holding that the plaintiffs' evidence was unreliable, we and other circuits relied on specific factual findings as to what constituted generally accepted scientific methodology. *Id.* at 1130-31. *See also Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, 311-13 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990); *DeLuca*, 911 F.2d at 949-52 (discussing Bendectin case law from other circuits). In *Daubert*, we upheld summary judgment based on the large volume of unfavorable epidemiological studies establishing the absence of causation. 951 F.2d at 1129. *See also Brock*, 874 F.2d at 311. In that case, "[p]laintiffs' evidence of causation consisted primarily of expert opinion based on *in vitro* and *in vivo* animal tests, chemical structure analyses and the reanalysis of epidemiological studies." The defendant's evidence included "the affidavit of a physician and epidemiologist who reviewed all of the available literature on the subject, which included more than 30 published studies involving over 130,000 patients, and concluded that no published epidemiological study had demonstrated a statistically significant association between Bendectin and birth defects." *Daubert*,

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whether the court found the affidavit admissible but concluded that the evidence was nonetheless insufficient to enable a jury to find causation. We need not resolve this ambiguity, however, because we conclude that the affidavit, taken on its own terms, established causation within a reasonable medical probability.

951 F.2d at 1129. Here, Collagen presented no facts contradicting Dr. Spindler's testimony.

We hold:

1. The order granting the defendant's motion for summary judgment is reversed.

2. The order denying a new trial is mooted.

3. The order denying the plaintiffs leave to designate additional experts is vacated for reconsideration in light of the reversal of summary judgment.

REVERSED AND REMANDED.

Kennedy v. Collagen Corporation, No. 91-15597

KOZINSKI, Circuit Judge, dissenting:

This is the heart of Dr. Spindler's affidavit:

> The existence of anti-histone antibody is *suspect* [sic] that her immune system was triggered by an external source, which *could have been* the bovine collagen injections in her case. . . .
>
> Mrs. Kennedy's medical history, records and current laboratory results are *consistent with a temporal relationship* between her injections and her medical condition, including a severe adverse reaction to Defendant's product, with systemic immune disorders and deteriorating medical condition and clinical symptoms.

ER, Tab D, at 17 (emphasis added). Dr. Spindler also adds that "[m]ore recently, I have obtained and evaluated current laboratory rests results for her, which reveal a change in her ANA, and in the existence of anti-centromere antibody, previously not present." *Id.* Nowhere does Dr. Spindler explain the meaning of "ANA" or "anticentromere antibody," nor does he intimate what

either of these has to do with plaintiff's case against the defendant.

Dr. Spindler's affidavit is simply too indefinite to establish a "reasonable medical probability" that Kennedy's disorder is in any way linked with defendant's collagen treatments; it is rank speculation. Under the substantive law of California, which we are bound to apply, Kennedy was obligated to put forth "a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Kennedy's reliance upon this affidavit was insufficient to carry her summary judgment burden. I would therefore affirm the judgment against her.

APPENDIX D

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 91-15597

D.C. No. CV-89-02331-CAL

CHARLOTTE KENNEDY; ROBERT L. KENNEDY,
Plaintiffs-Appellants,

v.

COLLAGEN CORPORATION,
Defendant-Appellee.

Appeal from the United States District Court for the
Northern District of California
Charles A. Legge, District Judge, Presiding

Argued and Submitted May 15, 1992
San Francisco, California

MEMORANDUM *

(Filed JUN 8 1992)

Before: FERGUSON, REINHARDT and KOZINSKI, Circuit Judges.

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* This disposition is not appropriate for publication and may not be cited to or by the courts of this circuit except as provided by the 9th Cir. R. 36-3.

The district court did not err in ruling that Kennedy had failed to present sufficient evidence of causation to survive summary judgment. Under California law, Kennedy was required to prove causation "within a reasonable medical probability." *Jones v. Ortho Pharmaceutical Corp.*, 163 Cal. App. 3d 396, 402 (1985). Her expert affidavits on causation, however, were either speculative, highly equivocal, or both. They thus provided an insufficient basis for a reasonable jury to find causation. *See id.* at 402-04; *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322-24 (1986).

The district court's denial of Kennedy's motion for a new trial based on newly discovered evidence was not an abuse of discretion; Kennedy failed to show that she had exercised due diligence in searching for, but not discovering, the evidence earlier. *Contempo Metal Furniture Co. v. East Texas Motor Freight Lines, Inc.*, 661 F.2d 761, 766 (9th Cir. 1981).

Kennedy's challenge to the district court's refusal to designate Dr. Spindler as an expert for trial is moot, as there will be no trial.

AFFIRMED.

APPENDIX E

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

No. C-89-2331-CAL

CHARLOTTE KENNEDY, *et al.*,
Plaintiffs,

v.

COLLAGEN CORPORATION,
Defendant.

ORDER ON MOTION FOR SUMMARY JUDGMENT

(Filed Dec. 10, 1990)

This is a product liability action, for injuries allegedly resulting to plaintiff Charlotte Kennedy from the use of defendant's product Zyderm Collagen Implant (ZCI). Mrs. Kennedy was treated with ZCI in 1982 as a cosmetic aid. By 1983 she developed systemic lupus erythematosus (SLE). She alleges that the SLE condition was caused by the ZCI. Her husband joins as a plaintiff, alleging loss of consortium.

I.

Defendant has moved for summary judgment, contending that there is no genuine issue of fact that palintiff's SLE was caused by ZCI. As discussed below, defendant's motion is accompanied by evidence demonstrating the lack of causal medical connection between ZCI and SLE.

Plaintiffs have opposed the motion, and their opposition includes a request for a continuance of the motion under Rule 56(f) of the Federal Rules of Civil Procedure. Their opposition and request for continuance pri-

marily concern the late offer by plaintiffs of evidence from Dr. Joseph Spindler. This court received Dr. Spindler's affidavit at the oral argument of the summary judgment motion. Plaintiffs also request leave of the court to designate Dr. Spindler as an additional expert witness for trial, since expert designations were concluded in October 1989.

II.

The primary issue in this case, and this motion, is medical causation. However, because of plaintiff's request for a continuance, the late filing of Dr. Spindler's affidavit, and the request to designate Dr. Spindler as an additional expert for trial, it is necessary to review the procedural history of the case.

The action was originally filed in February 1988, and was assigned to another judge of this court. When the case was reassigned to the undersigned judge, a status conference was held on August 11, 1989. At the status conference, the court was advised that all discovery had been concluded, except discovery regarding experts. This court then set the following deadlines: designation of experts by October 1989, a discovery cutoff of November 1989, and trial in early 1990. On September 15, 1989, on plaintiffs' motion, this court compelled that certain of defendant's medical files be produced to plaintiffs. In December 1989, plaintiffs' counsel withdrew from the case, and the trial date was therefore vacated. Several status conferences were held from January 1990 through May 1990 to allow plaintiffs time to obtain new counsel and for new counsel to become familiar with the case. New counsel appeared in May 1990. A scheduling and status conference was held in June, 1990, at which time the court set the trial date for early 1991.

Defendant filed this motion for summary judgment in October 1990, and the hearing was held on November 16, 1990. The motion was then submitted for decision. The court has reviewed the moving and opposing papers, the

record of the case, some subsequent communications sent to the court by plaintiffs and defendant, and the applicable legal authorities. The court concludes that plaintiffs' request for further accommodation must be denied, and summary judgment must be granted in favor of defendant.

III.

As stated, defendant contends that there is no genuine issue of material fact regarding the absence of causation between SLE and ZCI.

Plaintiffs' substantive claims are governed by California law. Under California law, in order to establish a prima facie case of product liability, plaintiffs must present sufficient evidence on the issue of medical causation. *Jones v. Ortho Pharmaceutical Corporation*, 209 Cal. Reptr. 456, 460 (1985): "The law is well settled that in a personal injury action causation must be proven within a reasonable medical probability based upon competent medical testimony. Mere possibility alone is insufficient to establish a prima facie case . . ."

Defendant's motion for summary judgment squarely raises the issue of whether a causal connection between ZCI and SLE can be demonstrated by plaintiffs within a reasonable medical probability and based upon competent medical testimony. The motion is accompanied by extracts from the depositions of physicians, previously designated as experts in this case. That testimony need not be discussed in detail. Suffice it to say that the motion and the testimony establish a prima facie case of the absence of medical causation.

IV.

Under the *Celotex* trilogy, *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986); *Matsushita Electric Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986); *Anderson v. Liberty Lobby Inc.*, 477 U.S. 242 (1986), the burden then shifts to plaintiffs to raise a genuine issue of material

fact on causation. Plaintiffs' written opposition to the motion, filed before the question of Dr. Spindler's affidavit arose, was based upon the testimony of their designated expert Dr. Tuffanelli. However, his testimony is equivocal. He stated, "so in my mind, until I see some good honest published data in that area, I will remain *unconvinced* that it (ZCI) is *not* causing these diseases (SLE)." Even that equivocal opinion was undercut by testimony from his deposition. He stressed that a causal connection was merely "possible." He testified that no scientific data exists that examine the incidents of autoimmune diseases in persons who have used ZCI, and that it would therefore be difficult for any expert to base an opinion on information reasonably relied upon by any expert in the field. He did not express an opinion on the probability of causation, and he indicated that causation theories are currently based upon speculation. This is not be evidence [sic] sufficient to meet the standard of Federal Rule of Evidence 703, and does not meet the standard of proof of medical causation required by California law. *Jones*, 209 Cal. Rptr. at 461.

Plaintiffs offered the affidavit of Dr. Spindler at the oral argument. And the court has reviewed and considered that affidavit. However, the court concludes that even Dr. Spindler's affidavit does not sustain plaintiffs' burden of establishing a genuine issue of material fact on causation. His opinion is based primarily on the temporal relationship between plaintiffs' use of ZCI and the development of her disease (*post hoc, ergo propter hoc*). The most that he can say is that the ZCI injections were "suspect," and that her condition "could have been" caused by taking ZCI. There do not appear to be any other laboratory tests of plaintiff, epidemiological evidence, or toxicological evidence upon which the opinion is based. Therefore, the court must conclude that even Dr. Spindler's affidavit does not create the genuine issue of material fact on medical causation necessary to defeat summary judgment.

V.

Plaintiffs seek leave to designate further experts, primarily Dr. Spindler, and to continue consideration of the motion for summary judgment. This request must be denied.

As the history of the case demonstrates, experts were designated over a year ago in October, 1989. And this court was generous to plaintiffs in staying and continuing the proceedings from December 1989 to May 1990, when plaintiffs' new attorney entered the case. The change of counsel might arguably be a ground for granting plaintiffs further accommodation to designate new experts. However, no attempt to designate other experts was made between the date that plaintiffs' new counsel entered the case in May of this year and the date of the oral argument of the summary judgment motion.

IT IS THEREFORE ORDERED that summary judgment be granted in favor of defendant and against plaintiffs.

Dated: December 10, 1990.

/s/ Charles A. Legge
CHARLES A. LEGGE
United States District Judge

APPENDIX F

[Filed Jan. 16, 1996]

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 91-15197

D.C. No. CV-89-02331-CAL

CHARLOTTE KENNEDY and ROBERT I. KENNEDY,
Plaintiffs-Appellants,

v.

COLLAGEN CORPORATION,
Defendant-Appellee.

ORDER

Before: FERGUSON, REINHARDT, and THOMPSON, Circuit Judges.

The panel as constituted in the above case has voted unanimously to deny the petition for rehearing. Judges Reinhardt and Thompson voted to reject the suggestion for a rehearing en banc and Judge Ferguson recommended the denial of the en banc request.

The full court has been advised of the suggestion for en banc hearing and no judge of the court has requested a vote on the suggestion for rehearing en banc. Fed. R. App. P. 35.

The petition for rehearing is denied and the suggestion for a rehearing en banc is rejected.

Supreme Court, U.S.
FILED
MAY 10 1996
CLERK

(2)

No. 95-1644

In The

Supreme Court of the United States

October Term, 1995

COLLAGEN CORPORATION,

Petitioner,

v.

CHARLOTTE KENNEDY AND ROBERT KENNEDY,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Do the Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act, 21 U.S.C. Sec. 360c et seq., preempt state law claims to recover damages for injuries caused by a medical device?

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MISCELLANEOUS

Is the FDA Protecting Consumers from Dangerous Off-Label Uses of Medical Drugs and Devices? House Rep. No. 102-1064, 102d Cong., 2d Sess 5

STATEMENT

The question of whether the Medical Device Amendments of 1976 ("MDA") preempt state damages actions is presently under review by this Court in *Medtronic v. Lohr*, No. 95-754 and No. 95-886, argued April 23, 1996.

The MDA preemption questions raised in *Medtronic* are analogous to those presented here by Petitioner in *Kennedy*. The two cases differ factually in that the Class III device in *Medtronic* was cleared for marketing under 21 U.S.C. Sec. 360(k), commonly known as the "510(k) process" for "substantially equivalent" devices, while Petitioner Collagen Corporation's Class III device (Zyderm) was cleared for marketing under the premarket application process of 21 U.S.C. Sec. 360c, commonly known as "PMA approval."

As Section 360k(a) of the MDA does not preempt state-law claims for personal injury, the manner in which a Class III device reaches the market would be immaterial for preemption purposes. *Medtronic* should answer many questions regarding federal preemption of state laws under the MDA as to Class III medical devices. But to the extent that *Medtronic* leaves open any question as to the scope of the MDA preemption, certiorari should nonetheless be denied in this case because the lower court correctly determined that the Kennedy's claims are not preempted by the MDA.

DISCUSSION

1. As with *Medtronic*'s pacemaker, the design of Collagen's Zyderm originated with the company, not with the FDA. The FDA allowed Petitioner Collagen to market a device with that design, but it did not *require* that particular design. "Pre-market approval" is merely what it says: marketing approval, not marketing requirements. The FDA has not established any design requirements for Collagen's Zyderm device.

Rather, the relevant inquiry is the federal requirements applicable to the device. Like the device in *Medtronic*, the Zyderm device at issue in this case is not subject to any counterpart requirements that preempt personal injury claims.

Similarly, the FDA approves a PMA product's labeling, but does not itself draft the labeling. The FDA also allows the manufacturer to add warning and contraindications to its product's labeling without prior approval from the agency. *See infra* at page 5. Once the PMA-approved device is marketed, it is subject to the same good manufacturing practice regulations and the same labeling regulations as any other Class III device.

2. *Kennedy*, in acknowledging and applying the applicable MDA provisions and regulations as an integrated whole, correctly holds that the MDA and its related regulations do not preempt personal injury claims such as those brought by Respondents.

Kennedy recognizes that while Congress may have provided for preemption of state law under Section 360k(a), it is not an unlimited preemption, particularly in

light of FDA regulations promulgated under the MDA. These regulations state that in order for there to be preemption of a state law claim, the FDA must have first established *specific* counterpart regulations applicable to a *particular* device. 21 C.F.R. Sec. 808.1(d). As *Kennedy* held, the Class III PMA-approval process is not a "specific regulation" applicable to a "particular device," and there are no specific regulations promulgated for the design, manufacture or labeling of Zyderm. Therefore, as to this medical device, there is no preemption of Respondents' causes of action.

Moreover, as *Kennedy* correctly recognizes, Section 360k(a) does not preempt state or local requirements of *general applicability* under Section 808.1(d) (i.e., requirements applicable to products in addition to medical devices), and state common law is law of general applicability not relating solely to or regulating any medical device, but other products as well.

Because Congress has charged the FDA with implementing and interpreting the MDA, the agency's position on MDA preemption is entitled to substantial deference. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-45 (1984). The FDA's position is "dispositive unless its interpretation is inconsistent with clearly expressed congressional intent." *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 714 (1985) (deferring to the FDA's position narrowly construing preemption of state and local regulations of blood donation centers, despite comprehensive federal regulation). Thus, *Kennedy*, properly follows 21 C.F.R. Sec. 808.1(d) and gives deference to the FDA under *Chevron*.

Kennedy was properly decided, for both analytical and public policy reasons. "Reasonable" assurance of safety and efficacy through the PMA-approval process is merely the beginning, not the end, of medical device considerations. Section 360k(a) was not intended to supplant a manufacturer's responsibility and liability to users of its medical devices.

The petition should be denied.

CORRECTION OF MISSTATEMENTS IN THE PETITION

As required under Rule 15.1, Rules of the Supreme Court, Respondents note the following misstatements appearing in the Petition for Writ of Certiorari, which bear, or may bear, on the issues presented by this case.

1. Throughout its Petition, Collagen Corporation cites to the federal regulations governing pre-market applications ("PMA") for Class III medical devices, 21 C.F.R. Sec. 814, et seq. As Collagen's medical device "Zyderm" is a Class III "PMA approved" device, the Petition creates the impression that Zyderm underwent the rigors of PMA approval under 21 C.F.R. Sec. 814, et seq. In fact, however, Zyderm was approved in 1981, but the applicable federal PMA regulations were not effective until 1986. As a result, the Class III PMA device involved in this action did *not* undergo the PMA approval process set out in 21 C.F.R. Sec. 814.20, et seq.

2. At Page 6 of its Petition, Collagen quotes certain written "conditions of approval" issued in the FDA's approval of Zyderm, which conditions (inter alia) require

FDA approval of any labeling changes that may affect the safety or effectiveness of the device. The Petition creates the illusion that Collagen was unable to add the autoimmune disease warnings that form the basis of Respondents' "failure to warn" claim below. Collagen's Petition omits the following subsequent portion of the subject "conditions of approval" which actually *authorizes* Collagen to add safety warnings without waiting for FDA approval:

> Changes in labeling . . . which enhance safety of the device or safety in the use of the device may be [made] prior to the receipt of a written FDA approval . . .
>
> Specific examples of changes permitted are:
>
> (1) Addition of warnings, contraindications or side effects.

As a result, Collagen Corporation was authorized to add autoimmune warnings to the device package labeling without waiting for FDA approval.

4. At Page 6 Collagen asserts that "Since 1981, Collagen has marketed Zyderm as a prescription-only medical device strictly in accordance with these conditions and other requirements imposed by the FDA." This assertion is incorrect. In 1991, Collagen's Zyderm devices were seized and partially destroyed by the FDA and the U.S. Department of Justice as misbranded, mislabeled and/or adulterated medical devices, due to Collagen's violations of package labeling/PMA regulations for the devices. Moreover, Petitioner Collagen Corporation actively promoted Zyderm for unapproved uses, in violation of FDA regulations. *See Is the FDA Protecting Consumers From*

Dangerous Off-label Uses of Medical Drugs and Devices?, House Rep. No. 102-1064, 102d Cong., 2d Sess. at 8-9, 24-28 (GPO 1992).

5. At Pages 6 and 7, Collagen states that in 1991, after 10 years of clinical experience, the FDA reaffirmed Zyderm's finding of safety and effectiveness. This statement is misleading. The FDA "re-review" was of Collagen's original PMA application materials based upon 1981 standards, *not* an update with a decade of additional information under 1991 standards. This "re-review" did nothing more than find that the original PMA had been properly processed accordingly to 1981 Section 360c standards.

CONCLUSION

This petition should be denied.

Respectfully submitted,

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IN THE
Supreme Court of the United States
OCTOBER TERM, 1995

COLLAGEN, CORPORATION,
Petitioner,

v.

CHARLOTTE KENNEDY, *et al.*,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

REPLY BRIEF

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REPLY BRIEF

DISCUSSION

1. The issue in this case is whether 21 U.S.C. § 360k(a) preempts common law claims challenging the safety or effectiveness of a medical device that the Food and Drug Administration ("FDA") has found to be safe and effective and has approved for marketing pursuant to the statutory premarket approval ("PMA") process under 21 U.S.C. § 360e(c). The Ninth Circuit decided this issue in a manner that squarely conflicts with decisions by the First, Third, Fifth, Seventh, and Eighth

Circuits. This conflict may or may not be effectively resolved by this Court's forthcoming decision in *Lohr v. Medtronic, Inc.*, Nos. 95-754 and 95-886, *argued*, April 23, 1996. If the conflict is not resolved in *Medtronic*, certiorari should be granted in this case to lay to rest a recurrent and important question of federal preemption.

In opposing certiorari, respondents do not deny the existence of a conflict. They argue only that the decision below was right (and, by implication, that the decisions of all other circuits to have considered this issue were wrong). Of course, for the reasons stated in the petition, Collagen disagrees. But the disagreement between the parties, mirroring the disagreement among the circuits, simply highlights the fact that this case involves a conflict that this Court ultimately must resolve. The circuits should not be left at loggerheads over a question of federal law that is so commonly litigated and has such significant consequences for a major regulated industry.

2. Respondents make three purportedly factual points that call for a reply.

a. Respondents point out, as if it matters, that FDA promulgated its final regulations setting forth the procedures to be followed in filing an application for premarket approval under 21 U.S.C. § 360e(c) only in 1986, several years after Zyderm and many other medical devices already had been approved pursuant to the PMA process. Br. in Opp. 4. That in no way detracts from the rigor of the PMA process as administered prior to 1986. Lacking established procedures, the FDA had asked applicants to "follow the pertinent parts of the regulations for new drug applications," Erickson Decl., Ex. 1, and to "us[e] the PMA formatting suggested by the Bureau of Medical Devices." *Id.*, Ex. 2. Collagen did so. *Id.* The statute itself sets forth the basic substantive requirements that a manufacturer must meet to secure premarket approval, see Pet. 4-5, and the record is

clear both that FDA enforced those requirements and that Collagen met them. Erickson Decl. 1-5.

b. Respondents state that although the FDA does impose requirements with respect to Collagen's labeling for Zyderm, Collagen is free to add "warnings, contraindications, or side effects." Br. in Opp. 5. That statement is factually inaccurate and legally irrelevant.

Respondents' statement is factually inaccurate because Collagen is empowered to add warnings or information about contraindications or side effects only after (1) filing a PMA supplement with the FDA identifying the proposed changes, explaining the basis for them, and stating when they are to go into effect, and (2) receiving an acknowledgement from the Bureau of Medical Devices. 21 C.F.R. § 814.39(d)(1).

Respondents' statement is legally irrelevant because the MDA preemption statute bars the states from imposing any requirement "which is different from, or in addition to, any [FDA] requirement." 21 U.S.C. § 360k(a). A requirement, imposed through state common law, that Collagen add warnings not required by the FDA plainly would be "in addition to" the labeling requirements that the FDA does impose. *See King v. Collagen Corp.*, 983 F.2d 1130, 1139 (1st Cir.), *cert. denied*, 114 S.Ct. 84 (1993) (Aldridge & Campbell, JJ., concurring).

c. Respondents refer to a seizure by the FDA of Collagen's Zyderm devices in 1991. Br. in Opp. 5-6. This reference is purely inflammatory. The seizure itself was a trivial episode, it occurred long after the events giving rise to this litigation, it has nothing to do with respondents' claims, and for these reasons there understandably is no discussion of it in the record. The seizure took place merely because a line of text (nine words) had been inadvertently omitted in 1991 from the package inserts that accompanied the product. This problem, which was promptly rectified, has no bearing on the question presented in this case.

CONCLUSION

The petition should be held pending disposition of *Medtronic*; it should then be granted to the extent that the preemption issues it raises are left unresolved by the Court's decision in that case.

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